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By:

Sarah M. Barnett
Sarah M. Barnett

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application No.	09/986,509
Filing Date	November 9, 2001
First Named Inventor	Graham E. KELLY
Art Unit	1616
Examiner Name	Edward J. WEBMAN
Attorney Docket Number	07579.0006-01000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No.	Document Number Number-Kind Code (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
<i>J</i>		US 6,261,565	07-17-2001	Empie et al.	
<i>J</i>		US 2005/0131047	06-16-2005	Kelly et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
<i>J</i>		EP 0 682 877 B1	04-02-2003	Nichimo Co. Ltd.		
<i>J</i>		JP 01-258669	10-16-1989	Kikkoman Corp.		Abstract
<i>J</i>		WO 97/46208 A2	12-11-1997	Mt. Sinai School of Medicine of the City of New York		
<i>J</i>		WO 98/04248 A1	02-05-1998	Energetics, Inc.		
<i>J</i>		WO 98/21946 A1	05-28-1998	Internutria, Inc.		
<i>J</i>		WO 98/25588 A1	06-18-1998	Gorbach		
<i>J</i>		WO 99/45923 A1	09-16-1999	Merck & Co., Inc.		
<i>J</i>		WO 99/48496 A1	09-30-1999	Novogen Research Pty. Ltd.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
<i>J</i>		"Novogen launches Rimostil," Press Release, 2 pages, http://www.novogen.com/news/newsPopup.cfm?id=22 (June 22, 2000).	
<i>J</i>		BERKOW, R. (Ed.) et al., <u>The Merck Manual of Diagnosis and Therapy</u> , 16 th Ed., Merck Research Laboratories, Rahway, N.J., pp. 1357-1359, 1793-1795 (1992).	
<i>J</i>		BUDAVARI, S. (Ed.) et al., <u>The Merck Index</u> , 11 th Ed., Merck & Co., Inc., Rahway, N.J., p. 663, Monograph No. 4157 (1989).	
<i>J</i>		KNIGHT, D.C. et al., "Phytoestrogens - A short review," <i>Maturitas</i> 22(3):167-175 (1995).	
<i>J</i>		MARKOVITS, J. et al., "Inhibitory Effects of the Tyrosine Kinase Inhibitor Genistein on Mammalian DNA Topoisomerase II," <i>Cancer Res.</i> 49:5111-5117 (1989).	
<i>J</i>		NAIM, M. et al., "Antioxidative and Antihemolytic Activities of Soybean Isoflavones," <i>J. Agric. Food Chem.</i> 24(6): 1174-1177 (1976).	
<i>J</i>		PRADHAN, S.N. (Ed.), <u>Pharmacology in Medicine: Principles and Practice</u> , SP Press Intl., Inc., Maryland, pp. 466-467 (1986).	

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				Examiner Name	Edward J. WEBMAN
Sheet	2	of	3	Attorney Docket Number	07579.0006-01000

NON PATENT LITERATURE DOCUMENTS		
		REYNOLDS, J. (Ed.), <u>Martindale: The Extra Pharmacopoeia</u> , 13th Ed., The Pharmaceutical Press, London, UK, pp. 856, 1060, 1169, and 1170 (1993).
		WANG, H.J. et al., "Isoflavone Content in Commercial Soybean Foods," <i>J. Agric. Food Chem.</i> 42:1666-1673 (1994)
		WINTROBE, M.M. (Ed.), <u>Harrison's Principles of Internal Medicine</u> , 7th Ed., McGraw Hill, Tokyo, Japan, pp. 1968-1969 (1974).
		International Search Report for PCT/AU98/00313, mailed on June 30, 1998, 3 pages.
		International Preliminary Examination Report for PCT/AU98/00313, dated April 14, 1999, 5 pages.
		EPO Supplementary Search Report for EP Appl. No. 98916669.9, dated May 26, 2003, 3 pages.
		EPO Examination Report for EP Appl. No. 98916669.9, dated October 27, 2003, 3 pages.
		Office Action issued in U.S. Application No. 09/077,590 on July 9, 1999 (Attorney Docket No. 07579.0006-00000).
		Office Action issued in U.S. Application No. 09/077,590 on April 27, 2000 (Attorney Docket No. 07579.0006-00000).
		Amendment and Response filed in U.S. Application No. 09/077,590 on October 27, 2000 (Attorney Docket No. 07579.0006-00000).
		Office Action issued in U.S. Application No. 09/077,590 on February 9, 2001 (Attorney Docket No. 07579.0006-00000).
		Amendment filed in U.S. Application No. 09/077,590 on May 31, 2001 (Attorney Docket No. 07579.0006-00000).
		Office Action issued in U.S. Application No. 09/647,092 on October 23, 2001 (Attorney Docket No. 07579-0013-00000).
		Amendment filed in U.S. Application No. 09/647,092 on March 25, 2002 (Attorney Docket No. 07579-0013-00000).
		Office Action issued in U.S. Application No. 09/647,092 on June 18, 2002 (Attorney Docket No. 07579-0013-00000).
		Amendment and Response After Final filed in U.S. Application No. 09/647,092 on December 17, 2002 (Attorney Docket No. 07579-0013-00000).
		Notice of Allowance and Notice of Allowability with Statement of Reasons issued in U.S. Application No. 09/647,092 on April 8, 2003 (Attorney Docket No. 07579-0013-00000).
		Office Action mailed in U.S. Patent Application No. 10/459,537 on December 20, 2005 (Attorney Docket No. 07579-0013-01000).
		Office Action issued in U.S. Patent Application No. 09/914,035 on December 18, 2002 (Attorney Docket No. 07579-0015-00000).
		Office Action issued in U.S. Patent Application No. 10/600,004 on June 17, 2004 (Attorney Docket No. 07579-0015-01000).
		Amendment and Response filed in U.S. Patent Application No. 10/600,004 on December 13, 2004 (Attorney Docket No. 07579-0015-01000).
		Final Office Action issued in U.S. Patent Application No. 10/600,004 on April 13, 2005 (Attorney Docket No. 07579-0015-01000).

Examiner Signature		Date Considered	7/06
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE
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Sheet

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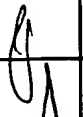
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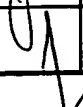
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 Amendment after Final filed in U.S. Patent Application No. 10/600,004 on October 12, 2005
(Attorney Docket No. 07579-0015-01000).

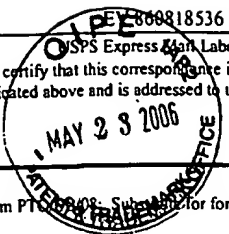
 Advisory Action issued in U.S. Patent Application No. 10/600,004 on November 16, 2005
(Attorney Docket No. 07579-0015-01000).

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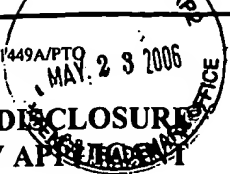
By: Cheryl L. Franke
 Cheryl L. Franke

IDS Form PTO 1449A-PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
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			Filing Date	November 9, 2001	
			First Named Inventor	Graham E. KELLY	
			Art Unit	1616	
			Examiner Name	Edward J. WEBMAN	
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Sheet	1	of	4		

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
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		Number-Kind Code (if known)			
2		US 2002/0198248 A1	12-26-2002	Kelly et al.	
		US 2003/0018060 A1	01-23-2003	Kelly et al.	
		US 2003/0059384 A1	03-27-2003	Kelly et al.	
		US 2003/0078214 A1	04-24-2003	Kelly	
		US 2003/0157225 A1	08-21-2003	Husband et al.	
		US 2003/0219499 A1	11-27-2003	Kelly et al.	
		US 2004/0048812 A1	03-11-2004	Kelly	
		US 2004/0072765 A1	04-15-2004	Kelly et al.	
		US 2004/0106561 A1	06-03-2004	Kelly	
		US 2004/0116498 A1	06-17-2004	Husband	
		US 2004/0147551 A1	07-29-2004	Heaton et al.	
		US 2004/0152761 A1	08-05-2004	Heaton et al.	
		US 2004/0170713 A1	09-02-2004	Kelly	
		US 2005/0036962 A1	02-17-2005	Kelly et al.	
		US 2005/0059616 A1	03-17-2005	Kelly et al.	
		US 2005/0143588 A1	06-30-2005	Heaton et al.	
		US 4,379,177	04-05-1983	McCoy et al.	
		US 5,153,230	10-06-1992	Jaffery	
		US 5,424,331	06-13-1995	Shlyankevich	
		US 5,498,631 B1	03-03-1998	Gorbach et al.	
	US 5,523,087	06-04-1996	Shlyankevich		
	US 5,637,598	06-10-1997	Grese		
	US 5,855,892	01-05-1999	Potter et al.		
	US 6,033,714	03-07-2000	Gugger et al.		
	US 6,060,070	05-09-2000	Gorbach		

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Sheet 2 of 4				First Named Inventor Graham E. KELLY	Art Unit 1616
				Examiner Name Edward J. WEBMAN	Attorney Docket Number 07579.0006-01000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
J		US 6,235,773 B1	05-22-2001	Bissett	
J		US 6,599,536 B1	07-29-2003	Kelly et al.	
		US 6,642,212 B1	11-04-2003	Kelly	
		US 6,649,648 B1	11-18-2003	Kelly et al.	
		US 6,987,098 B2	01-17-2006	Kelly	
J		US 7,033,621 B1	04-25-2006	Kelly et al.	

FOREIGN PATENT DOCUMENTS						
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J		AU 1997-40034 B2	03-19-1998	Novogen Research Pty. Ltd.		
J		EP 0 412 211 A1	02-13-1991	Therapeutical Systems Corp.		
		WO 98/08503 A1	03-05-1998	Novogen Research Pty. Ltd.		
		WO 98/50026 A1	11-12-1998	Novogen, Inc.		
		WO 99/11260 A1	03-11-1999	Pfizer, Inc.		
		WO 99/11263 A1	03-11-1999	Pfizer Products Inc.		
		WO 99/36050 A1	07-22-1999	Novogen Research Pty. Ltd.		
		WO 99/49862 A1	10-07-1999	The University of Mississippi		
		WO 00/16759 A2	03-30-2000	Schnyder		
		WO 00/49009 A1	08-24-2000	Novogen Research Pty. Ltd.		
		WO 00/54753 A2	09-21-2000	Johnson & Johnson Consumer Companies, Inc.		
J		WO 00/64438 A1	11-02-2000	Novogen Research Pty. Ltd.		

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J		BABER, R. et al., "The effect of an isoflavone dietary supplement (Rimostil™) on serum lipids, forearm bone density and endometrial thickness in post-menopausal women," <i>10th Annual Meeting of the North American Menopause Society</i> , New York, 4 pages (1999).	
J		CASWELL, A. (Ed.) "Hypolipidaemic agents," <i>MIMS Annual</i> , 23rd Edition, pp. 2f-152 to 2f-168, Tien Wah Press, Singapore (1999).	
J		CHAN, K. et al., "Inhibitors of hydroxymethylglutaryl-coenzyme A reductase and risk of fracture among older women," <i>Lancet</i> 355:2185-2188 (2000).	

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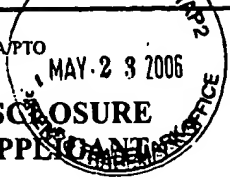
NON PATENT LITERATURE DOCUMENTS

1	CHANG, Y-C. et al., "Microwave-mediated synthesis of anticarcinogenic isoflavones from soybeans," <i>J Agric. Food Chem.</i> 42:1869-1871 (1994).	
2	Chicago Center for Clinical Research, Company Press Release, March 13, 2000, "Chicago Center for Clinical Research study suggests new, more effective way to treat older women with high cholesterol," 1 page.	
	CLIFTON-BLIGH, P. et al., "The effect of isoflavones extracted from red clover (Rimostil™) on lipid and bone metabolism," <i>Menopause</i> 8(4):259-265 (2001).	
	DÖREN, M. et al., "Identification and treatment of postmenopausal women at risk for the development of osteoporosis," <i>Intl. J. Clin. Pharmacology, Therapy and Toxicology</i> 30(11):431-433 (1992).	
	DUBEY, R. et al., "Phytoestrogens inhibit growth and MAP kinase activity in human aortic smooth muscle cells," <i>Hypertension</i> 33(Part II):177-182 (1999).	
	EVANS, D. et al., "Ovarian cancer family and prophylactic choices," <i>J. Medical Genetics</i> , 29:416-418 (1992).	
	GOH, J. et al., "Postmenopausal endometrioma and hormonal replacement therapy," <i>Aust. NZ J. Obstet. Gynaecol.</i> 32(4):384-385 (1992).	
	GOLDMAN, L. et al., "Cost and health implications of cholesterol lowering," <i>Circulation</i> 85:1960-1968 (1992).	
	GRAHAM, T., "Flavonoid and isoflavonoid distribution in developing soybean seedling tissues and in seed and root exudates," <i>Plant Physiol.</i> 95:594-603 (1991).	
	GRODSTEIN, F. et al., "Postmenopausal hormone use and cholecystectomy in a large prospective study," <i>Obstet. Gynecol.</i> 83(1):5-11 (1994).	
	GUGGOLZ, J. et al., "Detection of daidzein, formononetin, genistein, and biochanin A in forages," <i>Agr. Food Chem.</i> 9(4):330-332 (1961).	
	HEBERT, P. et al., "Cholesterol lowering with statin drugs, risk of stroke, and total mortality. An overview of randomized trials," <i>JAMA</i> 278(4):313-321 (1997).	
	HULLEY, S. et al., "Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women," <i>JAMA</i> 280(7):605-613 (1998).	
	KELLY, S. et al., "Protein tyrosine phosphorylation mediates TNF-induced endothelial-neutrophil adhesion in vitro," <i>Am. J. Physiol.</i> 274 (Heart Circ. Physiol. 43):H513-H519 (1998).	
	MAY, M. et al., "Effects of protein tyrosine kinase inhibitors on cytokine-induced adhesion molecule expression by human umbilical vein endothelial cells," <i>Br. J. Pharmacol.</i> 118:1761-1771 (1996).	
	NESTEL, P. et al., "Isoflavones from red clover improves systemic arterial compliance but not plasma lipids in menopausal women," <i>J. Clin. Endocrinology and Metabolism</i> 84(3):895-898 (1999).	
	PALMETSHOFER, A. et al., "α-Galactosyl epitope-mediated activation of porcine aortic endothelial cells," <i>Transplantation</i> 65(7):971-978 (1998).	
2	PANCHAGNULA, R. et al., "Transdermal iontophoresis revisited," <i>Curr. Opin. Chem. Biol.</i> 4:468-473 (2000).	

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8		PARFITT, K. (Ed.), <u>Martindale, The complete drug reference</u> , 32nd Edition, Pharmaceutical Press, London, Table of Contents, p. vi (1999).	
8		PEDERSON, T. et al., "Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S)," <i>The Lancet</i> 344:1383-1389 (1994).	
		SACKS, F. et al., "The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels," <i>The New England Journal of Medicine</i> 335(14):1001-1009 (1996).	
		SAMMAN, S. et al., "The effect of supplementation with isoflavones on plasma lipids and oxidisability of low density lipoprotein in premenopausal women," <i>Atherosclerosis</i> 147:277-283 (1999).	
		SBAROUNI, E. et al., "The effect of hormone replacement therapy alone and in combination with simvastatin on plasma lipids of hypercholesterolemic postmenopausal women with coronary artery disease," <i>J. Am. Coll. Cardiol.</i> 32:1244-1250 (1998).	
		STAMPFER, M. et al., "A prospective study of cholesterol, apolipoproteins, and the risk of myocardial infarction," <i>The New England Journal of Medicine</i> 325(6):373-381 (1991).	
		TAMURA, S. et al., "Chemical studies on 'clover sickness;' Part I. Isolation and structural elucidation of two new isoflavonoids in red clover," <i>Agr. Biol. Chem.</i> 33(3):391-397 (1969).	
		WEI, H. et al., "Antioxidant and antipromotional effects of the soybean isoflavone genistein," <i>P.S.E.B.M.</i> 208:124-130 (1995).	
		WEIDENBÖRNER, M. et al., "Antifungal activity of isoflavonoids in different reduced stages on <i>Rhizoctonia solani</i> and <i>Sclerotium rolfsii</i> ," <i>Phytochemistry</i> 29(3):801-803 (1990).	
		WEINBERG, D. et al., "Identification and quantification of anticarcinogens in garlic extract and licorice root extract powder," <i>J. High Resolution Chromatography</i> 15:641-654 (1992).	
8		Amendment filed in U.S. Patent Application No. 10/600,004 on May 16, 2006 (Attorney Docket No. 07579-0015-01000).	

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